

effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 43400, Oct. 1, 1976; 42 FR 41855, Aug. 19, 1977; 45 FR 43402, June 27, 1980; 47 FR 14150, Apr. 2, 1982]

§ 522.775 Doxapram hydrochloride injection.

(a) *Specifications.* The drug is a sterile aqueous solution containing 20 milligrams doxapram hydrochloride per milliliter.

(b) *Sponsor.* See No. 000031 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Administer to dogs, cats, and horses to stimulate respiration during and after general anesthesia; to speed awakening and return of reflexes after anesthesia. Administer to neonate dogs and cats to initiate respiration following dystocia or caesarean section; to stimulate respiration following dystocia or caesarean section.

(2) For intravenous use in dogs and cats at a dose of 2½ to 5 milligrams of doxapram hydrochloride per pound of body weight in barbiturate anesthesia, 0.5 mg per lb. in gas anesthesia; for intravenous use in horses at 0.25 mg per lb. of body weight in barbiturate anesthesia, 0.2 mg per lb. in inhalation anesthesia, 0.25 mg per lb. with chloral hydrate with or without magnesium sulfate; for subcutaneous, sublingual, or umbilical vein administration in neonate puppies at a dose rate of 1 to 5 mg; for subcutaneous or sublingual use in neonate kittens at 1 to 2 mg. Dosage may be repeated in 15 to 20 minutes if necessary.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 17838, Apr. 23, 1975]

§ 522.784 Doxylamine succinate injection.

(a) *Specifications.* Each milliliter of the drug contains 11.36 mg of doxylamine succinate.

(b) *Sponsor.* See No. 011716 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in conditions in which antihistaminic therapy may be expected to al-

leviate some signs of disease in horses, dogs, and cats.¹

(2) It is administered to horses at a dosage level of 25 mg per hundred pounds of body weight. It is administered to dogs and cats at a dosage level of 0.5 to 1 mg per pound of body weight. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect. Intravenous route is not recommended for dogs and cats and should be injected slowly in horses. Intramuscular and subcutaneous administration should be by divided injection sites.¹

(3) Not for use in horses intended for food.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 42 FR 60140, Nov. 25, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996]

§ 522.800 Droperidol and fentanyl citrate injection.

(a) *Specifications.* Droperidol and fentanyl citrate injection is a sterile solution containing 20 milligrams of droperidol and 0.4 milligram of fentanyl citrate per cubic centimeter.

(b) *Sponsor.* See No. 000045 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs as an analgesic and tranquilizer and for general anesthesia.

(2) It is administered as follows:

(i) For analgesia and tranquilization administer according to response desired, as follows:

(a) Intramuscularly at the rate of 1 cubic centimeter per 15 to 20 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight, or

(b) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight.

(ii) For general anesthesia administer according to response desired, as follows:

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.